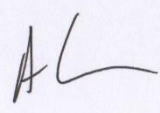# Statistical and Health Economics Analysis Plan (SHEAP) for

FluCare - feasibility

Title: Estimating the effectiveness and cost-effectiveness of a complex intervention to increase care home staff influenza vaccination rates – a feasibility study.

Trial registration ISRCTN 14727552

IRAS # 305371

Based on protocol version 1.0
Version of SAP: 1.0

Author	Title	Signature	Date
Allan Clark	Trial Statistician		04/05/22
Adam P Wagner	Trial Health Economist		04/05/22
Reviewers	Title	Signature	Date
Erika Sims			
Approver	Title	Signature	Date
Amrish Patel	Co-Chief Investigator		04/05/22
David Wright	Co-Chief Investigator		4/05/22

1 CONTENTS

2 INTRODUCTION

This is a brief statistical analysis plan for the feasibility study of the FluCare project.

3 TRIAL POPULATION

3.1 ANALYSIS POPULATION

The analysis population will be made up of

- all care home staff (including agency and volunteers as well as core staff) that we have either baseline or outcome data for.
- all care homes allocated to a treatment arm.

3.2 WITHDRAWAL/FOLLOW-UP

The numbers, with reasons, of loss to follow-up (drop-outs or withdrawals) over the course of the trial will be summarised by treatment arm. This will be reported at both staff and care home levels

3.3 BASELINE CHARACTERISTICS

Baseline data will be presented using summary statistics by allocated group, the mean and standard deviation shall be used for continuous variables and the number and percentage for categorical variables. If the continuous variables are heavily skewed then the median and interquartile range will be used. If necessary, levels of categorical variables may be combined for analysis. The table template is given below.

Table 1: Template for baseline table.

	Arm A	Arm B	Arm C	Arm D	Arm E
Age (years), mean (SD)					
Sex, n(%)					

Male				
Female				
Other				
Ethnicity, n(%)				
As defined in log				
English as a first language, n(%)				
Role				
Caregiver				
Previous vaccination rate of care home				
Size of care home				
Care home funding				
Care home location				

4 ANALYSIS

4.1 ANALYSIS METHODS

Feasibility outcomes:

The number of eligible care homes invited to participate will be tabulated and the percentage of those who consent to participate will reported along with reasons for not participating.

Retention rate will be estimated, as the percentage of staff who withdraw from follow-up from each arm. The number of care homes that withdraw will also be tabulated.

No formal hypothesis testing will be undertaken for any of the feasibility outcomes.

The template for reporting these outcome is given in Table 2.

Table 2: Template for feasibility outcomes

Outcome	Arm A	Arm B	Arm C	Arm D	Arm E
Trial retention rate					
Completeness of primary outcome (%)					
Completeness of variables requested (%)					
Number of homes reporting all variables requested.					
Implementing/actioning processes for giving					

staff videos and information					
No of vaccination clinics held					
Number (percentage) of MAQ completed at baseline					
Number (percentage) of MAQ completed at follow-up					

Efficacy outcome – vaccination rate:

The rate of vaccination reported by the care home log will be tabulated by arm. Part of the data quality progression criteria will be assessed by informally comparing to the vaccination rate from the NHS tracker dataset. Control arm bias will be assessed by informally comparing arms B, C and D to the usual care arm (A). The signal of efficacy will be assessed by comparing the rate in the intervention arm (E) to each control arm. The template for reporting the efficacy outcomes is given in Table 3.

Table 3: Template for efficacy outcomes (descriptive statistics)

Outcome	Arm A	Arm B	Arm C	Arm D	Arm E
Vaccination rate (logs)					
Vaccination rate (NHS tracker dataset)					

Mechanism of Action Questionnaire MAQ analysis

The Mechanism of Action Questionnaire for FluCare has 5 statements (related to barriers to getting the vaccine) asking intervention recipients to rate the extent to which they are affected by the barrier using a 5-point Likert scale. Each statement will be summarised separately at baseline and outcome for each arm. The change-from-baseline will also be presented. No formal comparisons will be made between arms.

4.2 HEALTH ECONOMIC ANALYSIS

The health economic component's focus in the feasibility phase is to monitor data collection on individual staff, care homes and intervention resource use. Resulting findings will inform refined collection in the main trial, finalising data to be collected for its proposed health economic cost-and-consequences analysis.

Staff level data will be collected from the 'staff logs'. Descriptive statistics will be used to characterise staff (demographics, job role and working time), along with rates of sickness and leave

(both paid and unpaid) and vaccination rate. These will be presented inline with the SAP. Rates and patterns of missingness will be used to refine the design of the staff log for the main trial.

Potential impacts on care home level resident health will be collected from the 'Residents' Health Log'. Rates of mortality, hospital attendances and admissions, GP and Practice Nurse consultations will be summarised using descriptive statistics. Rates and patterns of missingness will be used to refine the design of the log for use in the main trial.

Drawing on data collected within the process evaluation, and expert opinion as needed, we will estimate the resources (eg staff time and vaccination materials) required to deliver elements of the FluCare intervention. Indicative costs of these resources will be estimated using standard costing resources (such as PSSRU) for the latest cost year available at time of analysis. Given the intervention impacts on a range of perspectives, a range of costing perspectives will be considered (including: NHS, public sector, care homes and pharmacies). Should the process evaluation highlight unintended consequences of the intervention, we will explore potential resource and cost impacts (for example, care home staff engaging with FluCare components on their own time).

5 STATISTICAL SOFTWARE

The statistical analysis will be undertaken by Allan Clark and will use Stata version 17, however, other packages such as R or SAS may be used if necessary. Health economic analysis will be undertaken by Adam Wagner, primarily using Excel and R, but utilising other packages if needed.